



Peer review af dimethoat, problemer med risikovurdering

Jensen, Bodil Hamborg; Petersen, Annette

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NOTAT

Til Fødevarestyrelsen

Vedr. Peer review af dimethoat, problemer med risikovurdering

Fra Fødevareinstituttet

7. januar 2019

J.nr. 19/00073

bhje/annp

Forespørgsel

I forbindelse med EFSA's konklusion for "Conclusion on the Peer review of the pesticide risk assessment of the active substance dimethoate" spørger MST/FVST, om der er vist sikker anvendelse for brug af dimethoat, og om vi ser mulighed for "risk mitigering" af eventuelle problemer. Der efterspørges en kort tekst.

Konklusion

Repræsentative brug for fornyelse af dimethoate er på hvede, rug, tritcale, durum hvede, sukkerroer, majroer og rødbeder. I Danmark er stoffet ikke godkendt til brug.

ADI kunne ikke fastsættes endeligt for dimethoat, da det ikke kunne afvises, at stoffet er genotoksisk. Omethoat er vurderet at være mutagent in vivo, så fastsættelse af toksikologiske reference værdier er ikke vurderet som muligt at fastsætte.

Da det ikke kan udelukkes, at dimethoat er genotoksisk, og omethoat er vurderet at være mutagent in vivo, og der derfor ikke kan fastsættes toksikologiske reference værdier for de to stoffer, vurderer DTU, Fødevareinstituttet, at der med de foreliggende data ikke er vist sikker anvendelse af dimethoat.

Vurdering af om der er vist sikker anvendelse

Dimethoat er under fornyelse, og EFSA har udarbejdet rapport for fornyelsen: Conclusion on the peer review of the pesticide risk assessment of the active substance dimethoate".

ADI kunne ikke fastsættes endeligt for dimethoat, da det ikke kunne afvises at stoffet er genotoksisk. Omethoat er vurderet at være mutagent in vivo, så fastsættelse af toksikologiske referenceværdier vurderes derfor ikke som muligt at fastsætte.

Restdefinitionen til monitorering er foreslået at være dimethoat og omethoate, idet der måles for dem særskilt.

Restdefinitionen til risikovurdering er provisorisk foreslået dimethoate og omethoat.

Datamangler nævnt i EFSA's opinion

Since a mutagenic potential could not be excluded for dimethoate, toxicological reference values could not be established and a dietary risk assessment for the consumers could not be conducted.

Furthermore, since omethoate was concluded to be an in vivo mutagen, the setting of toxicological reference values for this metabolite is not considered appropriate. This leads to a critical area of concern (see also Section 2).

Critical areas of concern

- Positive gene mutation effects were observed in bacterial and mammalian cells in vitro with dimethoate without appropriate in vivo follow-up (see Section 2).
- Omethoate was concluded to be an in vivo mutagen, no threshold for this effect is assumed and the setting of toxicological reference values for this metabolite is not considered appropriate (see Sections 2 and 3).
- Since a mutagenic potential could not be excluded for dimethoate, no threshold for this effect is assumed and therefore toxicological reference values could not be established. Dietary and non-dietary exposure risk assessment could not be conducted (see Sections 2 and 3).

Mulighed for eventuel "risk mitigering" af eventuelle problemer

Da datamangler er vedr. fastsættelse af toksikologiske referenceværdier, ses der umiddelbart ikke nogen mulighed for risk-mitigering.

Referencer

Conclusion on the Peer review of the pesticide risk assessment of the active substance dimethoate, EFSA 2018